

CLAIMS:

1. A method of modulating an allergic response of an individual comprising the step of delivering an allergen directly into a lymph node of said individual, whereby the allergic response is modulated.
- 5 2. The method of claim 1 wherein said lymph node is an axillary lymph node.
3. The method of claim 1 wherein said lymph node is an inguinal lymph node.
4. The method of claim 1 wherein the allergen is delivered to an antigen presenting cell within the lymph node.
5. The method of claim 1 wherein the allergen is delivered to an immune cell
- 10 within the lymph node.
6. The method of claim 1, further comprising the step of using an ultrasound device to monitor location of an injection needle.
7. The method of claim 1, further comprising the step of visualizing the lymph node using a radiological method.
- 15 8. The method of claim 1 wherein the individual possesses defective lymph nodes.
9. The method of claim 1 wherein the allergen is an extract or a purified substance.
10. The method of claim 1 wherein the allergen is selected from the group consisting of allergenic components of bee venom, wasp venom, fire ant venom, pollen, mold, anesthetics, serum, drugs, animals, animal dander, cockroaches,
- 20 dust mites, food allergens, poison ivy, poison oak, poison sumac, viruses, bacteria, protozoa, and latex.
11. The method of claim 10 wherein the allergen is a food allergen and said food allergen is selected from the group consisting of milk, fish, shellfish, peanuts, tree nuts, honey, fruits, eggs, soy, and wheat.
- 25 12. The method of claim 10 wherein the allergen is pollen and the pollen is selected from the group consisting of grass pollen, tree pollen, and herb pollen.
13. The method of claim 1 wherein the allergen is selected from the group consisting of animal dander, cockroach droppings, and dust mites.
14. The method of claim 1 wherein the allergen is selected from the group
- 30 consisting of a recombinant protein and a synthesized peptide.

15. The method of claim 1 wherein the allergen is delivered to the lymph node by direct injection of a nucleic acid which encodes the allergen.
16. The method of claim 1 wherein the allergen is contained in an encapsulating material.
- 5 17. The method of claim 16 wherein the encapsulating material is selected from the group consisting of a polymeric material, an injectable gel, an injectable implant, a biodegradable polylactide-co-glycolide polyester (PLGA), a polyanhydride, a polysaccharide, a cellulose derivative, a protein, and a polyacrylate.
- 10 18. The method of claim 16 wherein the encapsulating material is in the form of a microsphere or nanosphere.
19. The method of claim 1 wherein the allergen further comprises a delivery substance.
20. The method of claim 1 wherein the allergen is accompanied by an adjuvant.
- 15 21. The method of claim 20 wherein the adjuvant is selected from the group consisting of alum, BCG, aluminum hydroxide, aluminum phosphate, calcium phosphate, a surface-active agent, a surface-active microparticle, a bacterial product, a chemokine, a cytokine, a hormone, chitosan, starch, alginate, a cellulose derivative, a protein, water, a saline solution, a dextrose solution, albumin, or a nucleic acid.
- 20 22. The method of claim 1 wherein the step of delivering is carried out at least twice.
23. The method of claim 1 wherein 1 to 5 doses of from about 0.01  $\mu\text{g}$  to about 10  $\mu\text{g}$  of the allergen are administered.
- 25 24. The method of claim 1 wherein a dose of from about 0.1  $\mu\text{g}$  to about 50  $\mu\text{g}$  of the allergen is administered.
25. The method of claim 1 wherein the allergen is delivered in fewer than about 10 doses.
26. The method of claim 1 wherein the allergen is delivered in from 1 to about 5
- 30 doses.

27. The method of claim 1 further comprising the step of detecting a reaction associated with modulation of the allergic response.
28. The method of claim 27 wherein detection of the reaction is by means of a skin test.
- 5 29. The method of claim 27 wherein detection of the reaction is by means of a controlled allergen exposure.
30. The method of claim 27 wherein the allergen is bee venom and wherein detection of the reaction is by means of a bee sting challenge.
- 10 31. The method of claim 1 further comprising the step of assaying a property associated with modulation of the allergic response.
32. The method of claim 1 wherein a detectable allergic response is eliminated.
33. The method of claim 1 wherein a detectable allergic response is diminished.
34. The method of claim 31 wherein the property is a lowered sensitivity to the allergen or to a cross-reactive allergenic agent.
- 15 35. The method of claim 31 wherein the property is an increase in the individual's specific IgG4 level from about 50 to about 500%.
36. The method of claim 31 wherein the property is a decrease in the individual's specific IgG4 level.
37. The method of claim 31 wherein the property is a change in the individual's IgG ratio.
- 20 38. The method of claim 31 wherein the property is lack of a significant increase in the individual's specific IgE level.
39. The method of claim 31 wherein the property is a decrease in the individual's specific IgE level.
- 25 40. The method of claim 31 wherein the property is a change in the individual's activated basophils.
41. The method of claim 31 wherein the property is a change in the individual's cytokine profile.
42. The method of claim 31 wherein the property is a change in the individual's Radio-Allergosorbent Test (RAST).
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43. A kit comprising (1) a composition comprising (a) an allergen and (b) a physiologically acceptable carrier and (2) instructions for the method of claim 1.
44. The kit of claim 43, further comprising a dual-chambered syringe.